(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19149, May 30, 1974, as amended at 49 FR 5097, Feb. 10, 1984; 50 FR 19921, May 13, 1985]

Subpart E—[Reserved]

Subpart F—Dermatologic Dosage Forms

§ 452.510 Erythromycin dermatologic dosage forms.

§ 452.510a Erythromycin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ointment is erythromycin in a suitable and harmless ointment base. It may contain suitable preservatives. Each gram of ointment contains 20 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain. The moisture content is not more than 1.0 percent. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1) (i), (iii), (iv), (v), (vii), and (viii).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, pH, moisture, residue on ignition, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the ointment in a separatory funnel containing 50 milliliters of reagent-grade petroleum ether. Shake until dissolved. Wash with four separate washings of a 4:1 mixture of methyl alcohol and distilled water. Combine the washings and bring to volume with the methyl alcohol-water solution in a volumetric flask. Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19149, May 30, 1974, as amended at 49 FR 5097, Feb. 10, 1984; 49 FR 47829, Dec. 7, 1984; 50 FR 47214, Nov. 15, 1985]

§ 452.510b Erythromycin topical solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin topical solution contains in each milliliter 15.0 or 20.0 milligrams of erythromycin. It may also contain one or more suitable and harmless solvents, surfactants, buffer substances, diluents, and perfumes. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain. If it contains 15.0 milligrams of erythromycin per milliliter, its moisture content is not more than 5.0 percent. If it contains 20.0 milligrams of erythromycin per milliliter, its moisture content is not more than 8.0 percent, except if it contains acetone, its moisture content is not more than 2.0 percent. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1), except heavy metals.

(2) *Packaging.* In addition to the requirements of § 432.1 of this chapter, it may either be dispensed on individually packaged pledgets, each individual pledget containing 0.8 milliliter of erythromycin topical solution, or in a jar containing 60 pledgets. The jar contains 0.8 milliliter of erythromycin topical solution per pledget. Although the pledgets in the jar are not individually packaged, the drug is uniformly distributed throughout the pledgets. The erythromycin topical solution used on the pledgets contains 20 milligrams of erythromycin per milliliter.